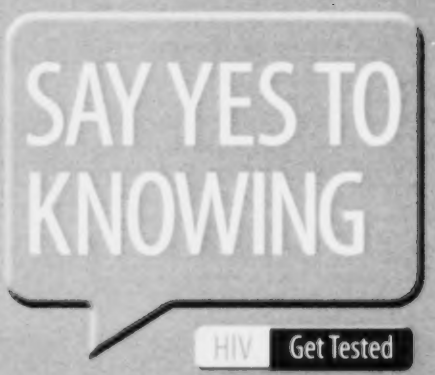
September 2008

Policies, Procedures and Quality Assurance for Point-of-Care HIV Testing in Ontario



Ontario

Table of Contents

Preface 1

Quality Assurance: Why It Matters II

Quality Assurance: A Shared Responsibility II

1. Personnel and Training Policies and Procedures 1

Policies 1

Responsibilities 1

Training/Certification 1

Record Keeping 1

Procedures 2

Conducting the Point-of-Care Test 2

Reading the Point-of-Care Test 2

Giving Test Results 2

Completing the HIV Test Requisition Form in Sites NOT Designated to Do Anonymous Testing 3

Completing the HIV Test Requisition Form in Sites Designated to Provide Anonymous Testing 4

Outreach Sites/Mobile Testing 5

Ordering AT Requisition Forms 6

2. Kit Lot Release Program 7

3. Internal Quality Control Policies and Procedures 8

Policies 8

Procedures 8

How to Validate a New Shipment of Kits 8

How to Run Routine Quality Controls 9

How to Handle an Invalid or Unacceptable Test Result when Validating Kits or Running Controls 9

How to Handle an Invalid or Unacceptable Test Result when Testing a Client 10

4. External Quality Assurance/Proficiency Testing 11

5. Parallel Testing Procedures 11

Procedures 12

How to Document and Compare Parallel Tests, and Detect and Report Discrepancies 12

6. Inventory Control 13

7. Equipment and Facilities 14

Temperature Control 14

Outreach Sites/Mobile Testing 14

8. Documents and Records 15

Policies 15

Templates 15

Appendix A: Point-of-Care Quality Assurance At a Glance 16

Who is Responsible for What? 16

Table 1: Quality Assurance Roles and Responsibilities in Point-of-Care HIV Testing 17

Appendix B: HIV Testing Requisition Form Algorithm 18

Appendix C: Documentation Templates 19

Point-of-Care (POC) HIV Testing Record – Daily Log 19

Monthly Summary Data Report 20

Quality Control Log 21

Incident Log 22

Environmental Monitoring Log 23

Preface

In June 2007, the Minister of Health and Long-Term Care announced a rapid point-of-care HIV testing program for Ontario. The Ministry of Health and Long-Term Care will supply point-of-care HIV tests to anonymous HIV test sites, public health sexual health clinics and community health centres in the province that choose to offer this service free of charge to the public.[1]

With point-of-care HIV testing, the screening test is done on-site while the client waits. People who test negative on the point-of-care test will know their HIV status within a few minutes of being tested and will not have to wait and return for the results (as is now required with standard laboratory HIV testing). People who test reactive on a point-of-care test will have a confirmatory test done using standard laboratory testing. The laboratory will expedite all reactive point-of-care confirmatory tests, and clinics will receive the results within one week.

This document sets out the policies and that procedures clinics are expected to follow to ensure the quality and consistency of their point-of-care HIV testing programs. It focusses only on the technical aspects of providing point-of-care HIV testing in Ontario. For information on pre- and post-test counselling and referrals, see the ministry document, *Guidelines for HIV Counselling and Testing* (2008).

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1 NOTE: Some sites serve specific populations and will not be offering point-of-care testing beyond their clinic base. To obtain information on locations and phone numbers of sites that will be providing point-of-care testing to the general public, contact the provincial AIDS Hotline at 416-392-2437 or 1-800-668-2437, French line 1-800-267-7432.

Quality Assurance: Why It Matters

Although the clinics and health centres offering point-of-care HIV testing do not fall under the *Laboratory Licensing and Inspection Act* or the Ontario Laboratory Accreditation (OLA) Program, the policies and procedures for point-of-care HIV testing have been developed based on the principals outlined in the OLA program requirements. Quality assurance is an important component of that program.

The overall goal of the Quality Assurance Program for point-of-care HIV testing is to ensure the delivery of consistently high quality, accurate and efficient HIV test results. Quality assurance programs are a series of planned activities that must be in place at all times to ensure that test results are accurate and as reliable as possible, and to ensure confidence in the testing program.

In the case of point-of-care HIV testing, these activities include:

- Personnel and training policies and programs.
- A kit lot release program.
- Internal quality control measures.
- External quality assessment/proficiency testing.
- Parallel testing procedures.
- Inventory control.
- Equipment and facilities.
- Documentation processes and records.

This document sets out the expectations for all these activities. It also provides a series of templates that sites can use to help monitor and ensure the quality of their point-of-care HIV testing program.

Quality Assurance: A Shared Responsibility

Quality assurance is a shared responsibility among the clinic/site staff, the Ministry of Health and Long-Term Care, and the manufacturer of the point-of-care HIV test kits. See Appendix A, Point-of-Care Quality Assurance at a Glance, for a summary of each partner's responsibilities in ensuring high quality point-of-care HIV testing in Ontario.

1. Personnel and Training Policies and Procedures

Policies

Responsibilities

An individual (i.e., quality assurance supervisor) must be assigned the overall responsibility for the quality and technical aspects of the site's point-of-care HIV testing program. This responsibility must be clearly identified in the person's job description, and it should include supervising all aspects of the point-of-care testing quality assurance program.

Individuals who will conduct point-of-care testing must have the responsibility specifically included in their job description.

Training/Certification

All staff responsible for conducting point-of-care HIV testing must have adequate training. The components of the training program should include:

- Biosafety.
- Performance of the test.
- Interpretation of results.
- Quality assurance and quality control procedures.

Before beginning to test clients, each trained staff person must correctly test and interpret the results of a competency assessment panel (i.e., blind panel of specimens) provided by the manufacturer. Once a person has passed the competency panel, the manufacturer will issue a certificate of competency. To order competency assessment panels, contact Bert Lozada, Manager of Shipping, bioLytical Laboratories directly at 604 204 6784 ext 245.

NOTE: The panels are shipped frozen and are good for three months if they remain frozen. If thawed, they last seven days in refrigeration at 2-8 °C.

Staff responsible for conducting point-of-care HIV testing must participate in periodic HIV testing continuing education. This may include sessions at HIV testing conferences, periodic teleconferences on point-of-care HIV testing, educational videos, or HIV testing information provided via websites.

All staff responsible for conducting point-of-care HIV testing must have the opportunity to participate in external proficiency programs on a rotating basis (see page 16).

Record Keeping

The clinic or centre must maintain records regarding each staff person's training, competency and ongoing education in point-of-care HIV testing either in personnel records or in a central quality assurance file.

Procedures

Conducting the Point-of-Care Test

Counsellors will follow the manufacturers' instructions (on the insert that comes with the point-of-care test kits) for taking the blood sample and conducting the test.

NOTE: The insert will be updated to include any new information and should be reviewed regularly.

The counsellor should have in the room with the client: vial 1, an alcohol swab, the lancet and the pipette. The counsellor may also have the receptacle or test well in the room with the client to demonstrate that it has been labelled correctly with his/her name or number.

The counsellor will take the blood sample using a finger prick.

NOTE: The test CANNOT be done using whole blood drawn through venipuncture.

Once the blood sample has been taken, the counsellor will take the receptacle or test well to the lab area or a separate room to complete the test. If a separate room is not available, the clinic will set up the testing space in a way that ensures the test analysis is done in a separate part of the room away from the client (e.g., behind a partition, using a cardboard barrier similar to those used for voting booths).

NOTE: No part of the analysis should be done in front of the client. If the client asks to see the test analysis, the counsellor may decide to show it, depending on his/her comfort level and providing he/she has completed analysis of a minimum of 25 tests.

If there is any problem taking the blood sample (e.g., not enough blood drawn), either obtain another biolytical manufactured lancet or pipette, or discard the entire test kit and start again with a new test kit.

NOTE: Always use a biolytical lancet and pipette. Never substitute with a lancet or pipette from another brand.

The ministry will supply additional biolytical pipettes and lancets for use exclusively with point-of-care test kits.

After completing the test, the counsellor should dispose of the test equipment as follows:

- Place the lancet in a sharps container.
- Dispose of vial 1, the pipette and the receptacle or test well with biohazardous waste.
- Recycle vials 2 and 3 (NOTE: vials 2 and 3 are NOT bio-hardardous and can be recycled).

Reading the Point-of-Care Test

It is recommended that two counsellors read all test results. If there is a problem reading the test (e.g., shadows or rings), then two counsellors MUST read the test.

If a control spot is not visible on the INSTI reaction well, the test should be considered INVALID and repeated.

Anything other than an absolute negative in the test spot area is considered reactive.

Any client who tests reactive must be tested again, using the standard HIV testing procedures, including obtaining informed consent for the confirmatory testing before drawing the blood. It is not necessary to have a signed consent form; the client's participation in testing implies informed consent.

Giving Test Results

Test results from point-of-care testing will be given to clients at the time of testing. The counsellor should take the receptacle or test well back into the room with the client, so the client can verify that the label is correct and see the result. ("This is your test result …")

- Clients who test negative will receive post-test counselling and be given a written copy of their test results, if requested.
- Clients who test negative who are high risk, symptomatic and in the window period will be told that they have tested negative, but that a sample of their blood will be taken for routine laboratory testing (i.e., standard HIV testing and p24 antigen testing; for more information on p24 antigen testing, see Guidelines for HIV Counselling and Testing, Ontario Ministry of Health and Long-Term Care, 2008).
- Clients who test reactive on the point-of-care test will be counselled. They will be told that standard HIV testing is required to determine whether or not they have HIV, and that they will have to return for the final test results in about two weeks time. Counsellors must obtain informed consent from clients before ordering the confirmatory testing.

NOTE: If a client who tests reactive declines confirmatory (standard) HIV testing, the counsellor should discuss the case with the clinic's medical director who will decide whether the point-of-care test result should be reported to public health.

Completing the HIV Test Requisition Form

A helpful HIV testing requisition form algorithm — for both point-of-care and standard HIV testing — is provided in Appendix B. The test requisition forms used are different depending on whether the site is designated for anonymous testing (AT). The following sections describe how to complete test requisition forms at non-AT and at AT sites.

1. In Sites NOT Designated to Do Anonymous Testing

Forms

Clinics will use the same test requisition form for point-of-care testing that they use to request standard HIV testing to provide epidemiological information on clients who choose point-of-care testing.

NOTE: Do not complete the "Surname" and "First Name", instead add a code in the "Patient Identifier" box (suggested code: person's initials and date of test). Also, do not collect "Date of Birth", instead collect "Year of Birth" and substitute "Year" for "Date" in the "Date of Birth" field.

NOTE: For blood samples taken under the Mandatory Blood Testing Act *2006, sites must use a separate HIV test requisition form. When this type of testing is requested, please contact the Central Public Health Laboratory for the requisition form.*

Point-of-Care Coloured Stickers

With each point-of-care test, the ministry will supply a set of three coloured stickers that sites will use on the test requisition form to communicate with the public health laboratory as follows:

- If the client tests negative on the point-of-care test, the counsellor will complete the HIV test requisition form as per the instructions above. Attach the **green sticker** (Point-of-Care Test Epi Info Only), and forward the form to the Public Health Laboratory. (No blood tube required.)
- If the client tests negative on the point-of-care test but is high risk, symptomatic **and** in the window period, then the counsellor will complete the HIV test requisition form as per the instructions above. Attach the **yellow sticker** (Point-of-Care Test Window Period), and forward the form to the Public

Health Laboratory, along with a tube of whole blood (red top vacutainer). The public health laboratory will do a STAT (i.e., priority) standard HIV test and a p24 antigen test.

- If the client tests reactive on the point-of-care test, the counsellor will complete the test requisition form, use the requisition form to request standard HIV testing, attach the **pink sticker** (Point-of-Care Test CONFIRMATORY), and forward the requisition to the Public Health Laboratory along with a tube of whole blood (red top vacutainer). The Public Health Laboratory will do a STAT standard HIV test.
- If the client tests "invalid" twice using the point-of-care test (see page 15), the counsellor will recommend that the client be tested using standard HIV testing, draw a venous blood sample (with client consent) and complete the test requisition form (no coloured sticker required). If the client does not consent to provide a venous blood sample, the counsellor will put the green sticker on the requisition form and write on the form that the point-of-care tests were invalid and that the client did not provide a blood sample.

Required Information for the Form

When completing the test requisition form, it is important to include the following information:

- the site address
- the information required to complete fields as per instructions above
- the right colour POC sticker
- the name of the ordering health care practitioner
- a clinic contact name if the counsellor is ordering a STAT test (i.e., a test to be given priority and completed quickly).

NOTE: The laboratory will do a STAT test for clients who test reactive on the POC test and for clients who test negative on the POC test and are in the window period (i.e., yellow and pink sticker tests). Results will be available within one week and will be phoned to the clinic.

2. In Sites Designated to Provide Anonymous Testing

Forms

Clinics will use the same AT test requisition form for point-of-care testing that they use to request standard AT HIV testing to provide epidemiological information on clients who choose point-of-care testing.

NOTE: Do not collect "Date of Birth", instead collect "Year of Birth" and substitute "Year" for "Date" in the "Date of Birth" field.

Site Number

Each anonymous testing (AT) clinic/site is assigned a site number by the ministry's Central Public Health Laboratory (CPHL) and this number, along with the address of the AT site, must appear on all anonymous test requisition forms, including those for clients who choose point-of-care testing. If an AT site provides service in more than one location and would prefer to have test results sent directly to each location, the CPHL will provide a site number for each location. To obtain individual site numbers for each location, send the contact names and address for each location to the central public health laboratory.

Outreach Sites/Mobile Testing

Some organizations may wish to conduct point-of-care testing at outreach sites or provide mobile services (e.g., vans).

The AIDS Bureau has established the following protocols and procedures for outreach/mobile testing:

- Transporting/storing supplies: Sites must maintain QC/QA measures wherever kits are stored (e.g., temperature monitoring), therefore kits cannot be stored overnight or for extended periods in unmonitored locations/spaces (e.g., vehicles).
- Testing space: Sites must attempt to create a space for staff to conduct and analyse the test, separate from the client, and provide staff with an appropriate surface on which to conduct the test to avoid spillage (e.g., flat, level surface). Staff may need a carrying case and clipboard.
- Second test-reader: All test result readers must have been certified through bioLytical's validation process, and must be properly trained.
- Single reader: A single reader may review test results, providing he/she is comfortable doing so and has analysed a minimum of 25 test results, which may include certification panels and control panels.
- Biohazardous waste disposal: Outreach sites must have biohazardous waste disposal capability (e.g., sharps container).
- Venipuncture: Outreach sites/mobile units should be equipped and staffed to provide clients with venipuncture testing on HIV POC reactive and window period results.

Patient Identification No.

AT test requisition forms (which are different from non-AT forms) are pre-numbered and come with three adhesive labels with the same number, which becomes the client's "Patient Identification No.".

For clients who choose point-of-care testing, counsellors will:

- write the "Patient Identification No." on the client's chart
- place one "Patient Identification No." label on the point-of-care test receptable
- place one "Patient Identification No." label on a card that is given to the client
- save one "Patient Identification No." label in case a tube of blood must be drawn and sent to the public health laboratory.

Counsellors will show the client the "Patient Identification No." on the chart, give the client the card (created by the clinic) with the "Patient Identification No." on it, and ask the client to keep the card. The card with the "Patient Identification No." is the only link to client's charts and results; however, counsellors should explain that, even if clients lose the card with their code number, they should still return to the clinic for their test results. If necessary, counsellors can use the date of their test and information on their chart or checklist to locate their chart. If clients have any concern about losing or misplacing the card with their code number, counsellors should suggest that they choose a code word that is easy for them to remember but will still ensure their anonymity (e.g., their mother's maiden name). Any code words chosen by a client should be recorded in the appointment log and/or client record.

Point-of-Care Coloured Stickers

With each point-of-care test, the ministry will supply a set of three coloured stickers that sites will use on the test requisition form to communicate with the public health laboratory as follows:

- If the client tests negative on the point-of-care test, the counsellor will complete the HIV test requisition form, attach the green sticker (Point-of-Care Test Epi Info Only), and forward the form to the Public Health Laboratory. (No blood tube required).
- If the client tests negative on the point-of-care test but is high risk, symptomatic and in the window period, then the counsellor will complete the HIV test requisition form, attach the yellow sticker (Point-of-Care Test Window Period), and forward the form to the Public Health Laboratory, along with a tube of whole blood (red top vacutainer). The public health laboratory will do a STAT standard HIV test and a p24 antigen test.
- If the client tests reactive on the point-of-care test, the counsellor will complete the test requisition form, use the requisition form to request standard HIV testing, attach the pink sticker (Point-of-Care Test CONFIRMATORY), and forward the requisition to the Public Health Laboratory along with a tube of whole blood (red top vacutainer). The public health laboratory will do a STAT standard HIV test.
- If the client tests "invalid" twice using the point-of-care test (see page 15), the counsellor will recommend that the client be tested using standard HIV testing, draw a venous blood sample (with client consent) and complete the AT test requisition form (no coloured sticker required). If the client does not consent to provide a venous blood sample, the counsellor will attach the green sticker (Point-of-Care Test Epi Info Only) to the AT requisition form and write on the form that the point-of-care tests were invalid and that the client did not provide a blood sample.

Required Information for the Form

When completing the test requisition form, it is important to include the following information:

- the AT site number
- the site address
- the information required to complete the form as per the instructions on page 8
- the right colour P&C sticker
- the name of the ordering health care practitioner
- a clinic contact name if the counsellor is ordering a STAT test (i.e., a test to be given priority and completed quickly).

The counsellor will also ensure that the "Patient Identification No." is affixed to the blood sample, and that it matches the number on the requisition form.

NOTE: The laboratory will NOT process the specimen if the AT requisition form is not complete. The form must have the client's year of birth, gender, risk factor(s), reason for testing, and the date of testing.

Ordering AT Requisition Forms

The AT requisition form has been revised. To order copies of the new form, complete the Ordering Anonymous HIV Serology Test Requisition Form. To obtain a copy of the order form, contact the central public health laboratory.

NOTE: If your site still has a supply of the old three-part form, you can continue to use those forms, and switch to the new form only when you need a new supply; however, you must use the coloured stickers on both the old and new form.

2. Kit Lot Release Program

Each lot or batch of test kits produced by the manufacturer must be assessed to ensure it meets performance specifications. Each individual clinic or centre will not keep enough stored samples to do this assessment, so the manufacturer has arranged for an independent third party laboratory assessment of each new kit lot released to Ontario sites.

For each lot delivered in Ontario, the manufacturer will provide a Certificate of Analysis (COA) describing the performance specifications as determined by the independent laboratory. The COA will be held by the AIDS Bureau, Ministry of Health and Long-Terms Care (MOHLTC).

Before using kits from a new lot, each site will ensure that the positive and negative controls are performing properly (see next page: How to Validate a New Shipment of Kits).

Record the lot number and expiry date stamped on the back of the kit package (NOT the expiry dates on any materials inside the kit) on your POC HIV Testing Record — Daily Log (see Appendix C).

3. Internal Quality Control Policies and Procedures

Policies

Sites must check each new shipment of point-of-care HIV tests to ensure that:

1. They have received their entire order.
2. The new kits are performing properly and have not been damaged in transit.

They must also regularly ensure that the point-of-care test kits they are using continue to perform properly.

The manufacturer will provide positive and negative control samples that the sites can use to test the point-of-care HIV test kits. This process is called "running controls". How frequently each site will run controls depends on the volume of point-of-care testing in each site.

- If a site conducts >24 point-of-care tests per day, the controls should be run every day.
- If a site conducts <24 point-of-care tests per day, the controls should be run approximately once per 24 specimens, but no less than once a week.
- If a site does no point-of-care tests in a given week, controls do not have to be run in that week. But in this case, controls must be run prior to conducting a client test, if it has been a week since the last controls were run.

All internal quality control results obtained from running controls as well as other relevant information (i.e., kit lot, tester, date and time) should be recorded. The quality assurance (QA) supervisor will monitor these results and records regularly (at least monthly).

Any incorrect quality control (QC) results should be brought immediately to the attention of the QA supervisor, who will investigate the incorrect QC result and document the results. If the problem cannot be identified or resolved (e.g., human error) the QA supervisor must stop all testing, and notify the AIDS Bureau and the Public Health Laboratory.

Procedures

Sites must use all the kits in one shipment before starting to use kits from a new shipment.

How to Validate a New Shipment of Kits

1. Record the lot number and number of tests received in the POC Inventory Log (see Appendix C) and in the online AIDS Bureau POC Inventory System.
2. Segregate newly received kits.
3. Set up a testing area for internal quality control testing.
4. Use one new device to test the positive control material, following the manufacturer's instructions.
5. Record the internal QC result for the positive control in the HIV POC Testing Record Daily Log and in the Quality Control Log (see Appendix C).
6. Use another new device to test the negative control material, following the manufacturer's instructions.
7. Record the internal QC result for the negative control in the HIV POC Testing Record Daily Log and in the Quality Control Log (see Appendix C).

If the internal QC results are acceptable (i.e., the positive produces a clear positive result, and the negative produces a clear negative result), the segregated kits can be released for use.

NOTE: If the results are not acceptable, i.e., if the testing results in an INCORRECT or INVALID test result for either one of the controls – the person running the controls must NOTIFY THE QA SUPERVISOR IMMEDIATELY (see How to Handle an Invalid or Unacceptable Test Result below).

NOTE: Control panels containing positive and negative specimens are shipped frozen, and last up to three months if they remain frozen. Once thawed, they last seven days in refrigeration at 2-8° C.

How to Run Routine Quality Controls

1. Set up testing area for internal quality control a testing.
2. Use one new device to test the positive control material, following the manufacturer's instructions.
3. Record the internal QC result for the positive control in the Quality Control Log (see Appendix C).
4. Use another new device to test the negative control material, following the manufacturer's instructions.
5. Record the internal QC result for the negative control in the Quality Control Log (see Appendix C).

If the results of the internal QC are acceptable (i.e., the positive produces a clear positive result and the negative is negative produces a clear negative result), testing of clients can proceed.

NOTE: If the results are not acceptable, i.e., if the testing results in an INCORRECT or INVALID test result for either one of the controls, the person running the controls must NOTIFY THE QA SUPERVISOR IMMEDIATELY (see How to Handle an Invalid or Unacceptable Test Result below).

How to Handle an Invalid or Unacceptable Test Result when Validating Kits or Running Controls

An invalid or unacceptable QC result indicates that there is a problem either with the testing process (e.g., human error), the control material or the testing device. All follow-up action must be carefully documented and involve the counsellor/tester and the supervisor. Use the following procedure when you receive an invalid result when

- validating a new shipment of kits and/or;
- running routine quality controls.

1. Record the unacceptable result (test 1) in the Incident Log. Be sure to describe the type of unacceptable result achieved and all of the follow-up activity.
2. Retain the devices used for the unacceptable QC testing.
3. Repeat the testing of both the positive and negative control material (test 2) using the same material and batch of kits. Ensure that the QC specimens are tested sequentially not simultaneously.
4. Record the results of test 2 in the Quality Control Log and the Incident Log.
5. If the results of test 2 are acceptable, carefully consider what might have occurred during the process that resulted in unacceptable results (e.g., mixed up QC materials, failed to add a test component), and testing of clients can proceed.

6. If the results of test 2 are unacceptable, repeat the testing of the positive and negative control material using fresh (unopened) control material (test 3). If the results of test 3 are acceptable, repeat the test once more (test 4) using the fresh control material. If the results are again acceptable, the problem is related to the control material, not the kits. Consider possible sources of error relating to the control material (e.g., became contaminated, improperly stored, temperature not controlled). Testing of clients can proceed.
7. If the results of test 3 or test 4 are unacceptable, ALL HIV POC TESTING MUST STOP. Notify:
   - The AIDS Bureau.
   - The Public Health Laboratory.
8. Retain all devices used when unacceptable results were obtained as they will be an important part of the investigation.
9. Compete the Incident Log fully and accurately because it will also be important to the investigation.
10. After consultation with other sites providing point-of-care HIV testing, the AIDS Bureau will notify the manufacturer for further action.

How to Handle an Invalid or Unacceptable Test Result when Testing a Client

An invalid or unacceptable result when testing a client may indicate a problem either with the testing process (e.g., human error), the blood sample or the testing device. Use the following procedure when you receive an invalid result when testing a client:

1. Record the invalid result (test 1) in the Incident Log. Be sure to describe the type of unacceptable result achieved and all of the follow-up activity.
2. Retain the devices used for the invalid testing.
3. Repeat the test (test 2), using a new kit.
4. If the results of test 2 are valid, carefully consider what might have occurred during the first test that might have led to an invalid result (e.g., inadequate sample, failed to add a test component) and proceed with client counselling and any additional testing (if result is reactive).
5. If the results of test 2 are invalid, record the results in the Incident Log and retain the testing devices.
6. Recommend that the person be tested using standard HIV testing, and draw a venous blood sample (with the client's consent).
7. Report the invalid test result to the QA supervisor who will investigate.
8. If more than 1 per cent of tests are invalid in one month of testing, the QA Supervisor must notify the AIDS Bureau.

4. External Quality Assurance/ Proficiency Testing

Each site will enroll in a proficiency testing program (using blind specimens sent twice per year). The AIDS Bureau will use the services of Quality Management Program — Laboratory Services (QMP—LS), a government agency responsible for external quality assurance, to provide proficiency testing.

All staff responsible for conducting point-of-care HIV testing will participate in proficiency testing on a rotating basis.

Any errors in proficiency will be investigated immediately. Corrective action must be taken and documented.

The clinic will maintain all proficiency testing records in a quality assurance file.

5. Parallel Testing Procedures

As part of quality assurance, point-of-care HIV test results should be compared regularly to the "gold standard" of HIV testing carried out by the public health laboratory in Ontario. Parallel testing allows sites to compare point-of-care HIV test results directly with those obtained by standard HIV screening and confirmatory testing.

Parallel testing will occur automatically for two categories of clients:

- For clients who test reactive on a point-of-care HIV test, a venous blood sample will be taken and forwarded to the public health laboratory for confirmatory testing.
- For clients who test negative, who are high risk, symptomatic **and** in the "window" period on a point-of-care HIV test, a venous sample will be taken and forwarded to the public health laboratory for standard HIV testing and a p24 antigen test.

The results from point-of-care and laboratory testing should be documented and compared, and any significant discrepancies (i.e., negative on point-of-care testing / positive on routine testing) should be brought to the attention of the AIDS Bureau and the public health laboratory.

The public health laboratory will tabulate parallel testing results for all sites monthly and will notify the AIDS Bureau and sites of any problems identified during data analysis.

Sites should also keep track of specific types of information locally, including:

- the proportion of HIV-negative clients who have a reactive point-of-care test result
- the proportion of invalid point-of-care tests.

If the data indicate that more than 0.5 per cent of tests were falsely reactive in one month of testing, the AIDS Bureau must be notified. If the data indicate that more than 1 per cent of tests were invalid in one month of testing, the AIDS Bureau must be notified.

Procedures

How to Document and Compare Parallel Tests, and Detect and Report Discrepancies

1. For all specimens forwarded to the public health laboratory for additional testing, record the details in POC HIV Testing Record — Daily Log (see Appendix C).
2. Record the public health laboratory results – including EIA, WB and p24 antigen (if done) — in the POC HIV Testing Record —— Daily Log (see Appendix C).
3. Compare point-of-care test results and public health laboratory results.

Below is a chart that illustrates different parallel test results and indicates the discrepant results that require action.

NOTE: A reactive point-of-care result with a negative HIV antibody laboratory result (i.e., false positive) is not unexpected. Up to 5 out of every 1000 negative people will test reactive on the point-of-care test even though they do not have HIV antibodies. This is NOT considered a discrepancy, but it is still important to track the occurrence of false reactive POC results. A negative point-of-care result with a positive HIV antibody laboratory test IS A SERIOUS DISCREPANCY. It means the point-of-care test produced a false negative result. This situation needs to be brought to the attention of the public health laboratory and the AIDS Bureau and, through them, to the manufacturer.

4. Report ANY false negative result on point-of-care testing to the supervisor, who will notify the AIDS Bureau and the public health laboratory immediately.

5. Complete the Monthly Summary Data Report (see Appendix C) and calculate the per cent of false reactive results and the proportion of invalid test results.

6. If > 0.5per cent of point-of-care tests are false reactive, notify the QA Supervisor, who will contact the AIDS Bureau and the public health laboratory.

7. If more than 1 per cent of tests are invalid, notify the AIDS Bureau.

POC Result	HIV Screen 1	HIV Screen 2	p24 Ag	WB	PHL Result	Discrepancy?	Action Required
Reactive	Reactive			Reactive	Positive	No	None
Reactive	Non-reactive	Non-reactive	Non-reactive	Non-reactive	Negative	No, but indicates POC false reactive	Track occurrence
Reactive	Reactive		Reactive	Indeterminate	Positive – Repeat	No	None
Negative	Reactive		+/-	Reactive	Positive	YES, indicates POC false negative	Notify PHL and AIDS Bureau
Negative	Non-reactive		Reactive	Non-reactive	Advise repeat	No, but client likely HIV+	No

6. Inventory Control

Clinics/sites must have a regular supply of point-of-care HIV test kits. It is imperative that they develop an inventory control process and use the online POC Inventory System established by the AIDS Bureau to keep track of product received, and the numbers of test kits used, including those for staff training, QC samples, EQA samples, client tests, invalid tests and spoiled test kits.

Given the importance of epidemiological data collection for monitoring the HIV epidemic, the AIDS Bureau will review supply requests against the number of test requisition forms submitted to the laboratory that have a point-of-care sticker. In cases where there is a significant discrepancy between the supplies requested and the submitted test requisition forms, the AIDS Bureau will follow up with the site, and supply requests will be withheld until the discrepancy is resolved.

7. Equipment and Facilities

Temperature Control

Sites will store and maintain the point-of-care HIV test kits at the temperature recommended by the manufacturer to avoid degradation. All rooms where the devices are stored must be monitored for temperature daily and records maintained. This can be done using a temperature monitoring device that records the minimum and maximum temperature achieved over a given period of time.

Organizations that offer point-of-care testing at multiple locations may either transport test kits to each location for immediate use or store a supply at the location. When considering storing POC kits at off-site locations, appropriate quality assurance policies and procedures must be implemented and maintained, including kit transportation, control specimen storage and site specific temperature monitoring (please review quality assurance procedures for storing and maintaining kits and quality control specimens).

Control panels containing positive and negative specimens are shipped frozen, and last up to three months if they remain frozen. Once thawed, they last seven days in refrigeration at 2-8 °C.

Outreach Sites/Mobile Testing

Some organizations may wish to conduct point-of-care testing at outreach sites or provide mobile services (e.g., vans).

The AIDS Bureau has established the following protocols and procedures for outreach/mobile testing:

- Transporting/storing supplies: Sites must maintain QC/QA measures wherever kits are stored (e.g., temperature monitoring), therefore kits cannot be stored overnight or for extended periods in unmonitored locations/spaces (e.g., vehicles).
- Testing space: Sites must attempt to create a space for staff to conduct and analyse the test, separate from the client, and provide staff with an appropriate surface on which to conduct the test to avoid spillage (e.g., flat, level surface). Staff may need a carrying case and clipboard.
- Second test-reader: All test result readers must have been certified through biolytical's validation process, and must be properly trained.
- Single reader: A single reader may review test results, providing he/she is comfortable doing so and has analysed a minimum of 25 test results, which may include certification panels and control panels.
- Biohazardous waste disposal: Outreach sites must have biohazardous waste disposal capability (e.g., sharps container).
- Venipuncture: Outreach sites/mobile units should be equipped and staffed to provide clients with venipuncture testing on HIV POC reactive and window period results.

8. Documents and Records

Policies

Clinics/sites must document all Quality Assurance Program procedures and maintain records for **10** years. All clinics/sites are expected to implement and maintain:

- standard operating procedures for point-of-care HIV testing
- records of staff training, competency and ongoing education
- client results recorded in the client file (along with kit lot, tester ID, date)
- a central log of testing results showing the date, kit lot, tester ID, client ID, relevant QC testing, as well as the results of parallel testing on all specimens forwarded to the public health laboratory for confirmatory or p24 antigen testing and any discrepancies
- a monthly summary of the number of false negative, false reactive and invalid results obtained through point-of-care testing
- an inventory control system to monitor kit lot and product availability
- an Incident Log, where all incorrect QC or other discrepancies, investigations and corrective actions will be recorded
- temperature control records or an environmental monitoring log for areas where the kits are stored
- QC results in a QC file that is reviewed by supervisory staff at regular intervals (i.e., at least monthly).

NOTE: Records are NOT to be submitted to the ministry (AIDS Bureau), but should be retained for periodic review by the ministry.

Templates

Templates have been designed to help clinics/sites maintain the documentation and records required to support an effective Quality Assurance Program (see Appendix C):

- Point-of-Care HIV Testing Record Daily Log
- Monthly Summary Report
- Quality Control Log
- Incident Log
- Environmental Monitoring Log.

Appendix A

Point-of-Care Quality Assurance At a Glance

Who is Responsible for What?

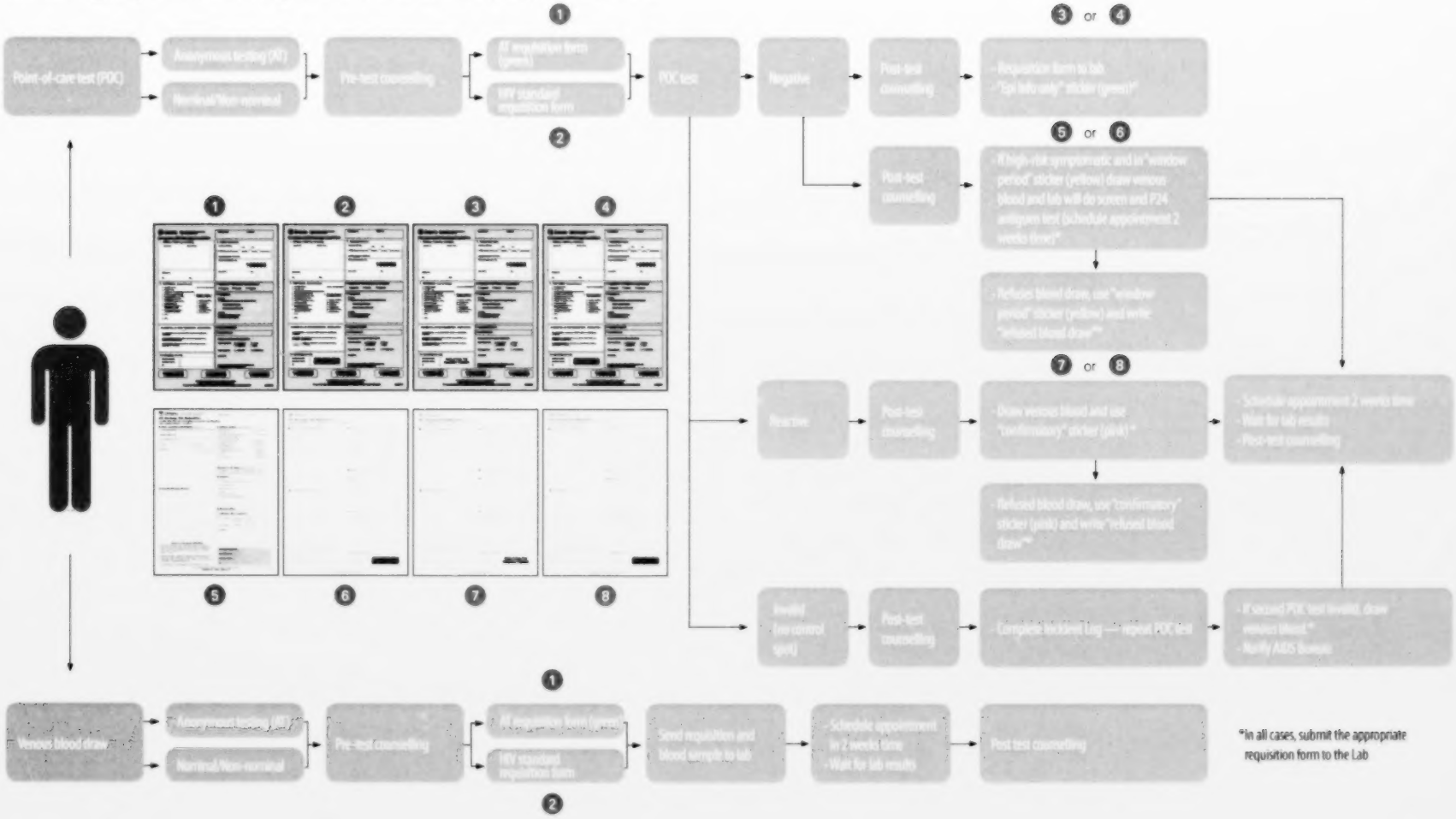
Quality assurance is a shared responsibility among the clinic/site and its staff, the Ministry of Health and Long-Term Care, and the manufacturer of the point-of-care HIV test kits. The following table (see page 17) outlines who is responsible for each aspect of the point-of-care HIV testing Quality Assurance Program.

Table 1: Quality Assurance Roles and Responsibilities in Point-of-Care HIV Testing

Activity	Supervisor	Counsellor/Tester	MOHLTC	Manufacturer
Training	Ensures staff are trained appropriately.	Participates in training program.	Provide initial training (AIDS Bureau).	Participates in initial training.
Competency Assessment	Ensures staff have passed their competency assessment before testing clients. Must retain records of competency for all staff.	Passes competency assessment before beginning testing on clients.		Provides assessment panels and certificates of competency on satisfactory completion of panel.
Refresher Training	Ensures staff have periodic refresher training. Must document refresher training for staff.	Participates in periodic refresher training.	Arranges periodic teleconference or in-person refresher/update discussions, training or provides educational materials for in-service education (AIDS Bureau).	
Job Descriptions	Ensures responsibilities for POC testing are delineated in job descriptions.			
Kit Lot Release Program	Ensures the Certificate of Analysis for each lot is available on site.	Runs QC specimens on each new kit lot, prior to using them to test clients.	Retains the original Certificate of Analysis for each kit lot number and makes a copy available for each site (Government Pharmacy).	Provides the Certificate of Analysis for each kit lot with each shipment to the Government Pharmacy.
Internal Quality Control	Reviews and approves internal QC records regularly and takes corrective action as required.	Runs positive and negative internal QC specimens provided by the manufacturer regularly (more every 24 specimens or once a week), records the results in QC logbook and testing logbook, and notifies supervisor of any discrepancies.		Responds to any issues related to Quality Control.
External Quality Assessment (EQA)	Ensures the site is enrolled in appropriate EQA program. Ensures all staff participate in EQA on a rotating basis. Reviews the results of EQA with staff, and takes corrective action if needed. Maintains EQA records.	Participates in EQA as required.	Provides direction on EQA opportunities (AIDS Bureau and public health laboratory).	Responds to any EQA issues related to kit performance.
Parallel Testing	Reviews results of parallel testing regularly, and notes and reports any issues related to kit performance to the AIDS Bureau, public health laboratory and manufacturer.	Records results of POC and PHL testing in a logbook, and tabulates monthly summaries of discordant results.	Provides monthly summaries of parallel testing results by site and provincially. Notes any trends in performance outside of manufacturer's specifications. (public health laboratory).	Responds to any concerns regarding kit performance.
Inventory Control	Ensures site participates in inventory control program. Authorizes kit ordering.	Tracks kit usage.	Provides data regarding testing. (public health laboratory). Authorizes kit release to sites (AIDS Bureau). Issues kits on AIDS Bureau approval. (Government Pharmacy).	
Environmental Monitoring	Ensures temperature charts are maintained daily for all areas where kits are stored or used. Reviews data regularly, and takes corrective action if required.	Completes daily temperature charts for all areas where kits are stored or used, notes any temperature outside the accepted range, and notifies supervisor.	Provides sites with requisite number of temperature gauges (AIDS Bureau).	
Documents and Records	Ensures all related quality documentation is appropriately tracked, filed and stored (for 10 years).	Completes all quality documentation as required.	Periodically audits sites to ensure QAP is appropriate.	

Appendix B

HIV Testing Requisition Form Algorithm (Point-of-Care (POC) and Standard



Appendix C

Documentation Templates

The following templates and forms will be available electronically. The following are examples of the forms and how to complete them.

Point-of-Care (POC) HIV Testing Record — Daily Log

Date	Client ID (name or AT #)	Risk	POC Kit Lot	POC Result		Referred to PHL for		If POC Result is Negative, Reason for Referral	PHL Result				Final Interpretation	False Positive?		Discrepancy? (False Negative)		Date Reported	Tester's Initials
				Neg	Reactive	HIV test	HIV-1 Ag		HIV-1/2 Screen Test	Supp HIV-1/2 EIA	HIV-1 Western Blot	HIV-1 p24 Ag		No	Yes	No	Yes		
Sep 5/07	123456	Sex with men	X249 Expires June 30, 2008	✓		Not Done	Not Done		Not Done	Not Done	Not Done	Not Done	HIV-1/2 + ves antibodies detected					Sep 7/07	AB
Sep 5/07	123456	Sex with men		✓		Done	Done	Dull, Risk and Symptomatic	NR	NR	Not Done	NR	HIV-1/2 + ves antibodies detected					Sep 11/07	CAS
Sep 5/07	123457 Repeat test	IDU		Invalid		Done		Invalid result. Confirmatory tests required	R	R	R		Invalid POC HIV-1 Antibody Positive	✓		✓		Sep 11/07	AB
Sep 5/07	123458	Sex with men			✓	Done			R	R	R		HIV-1 Antibody Positive	✓		✓		Sep 11/07	AB

Monthly Summary Data Report

Location: Hassle Free Clinic Site # XXXX Month: September Year: 2008

Total # of POC Tests Conducted	# POC Neg	# POC Neg Referred to PHL	# POC Reactive	# POC Invalid	# POC Neg, PHL Neg	# POC Neg, PHL Positive (false negatives)	# POC Reactive, PHL Positive%	# POC Reactive PHL Negative (false positive)	% of Tests False Positive	# POC Invalid, PHL Negative	# POC Invalid, PHL Positive	% of Tests Invalid

Quality Control Log

Location: Hassle Free Clinic Site #: XXXX Month: September Year: 2008

Date	QC Material	QC Lot #	Test Kit Lot #	Result	Tester ID	OK	Supervisor Review
Sep 5 2007	Negative	N0430 Expires Dec 15 2008	X240 Expires Nov 30 2008	Non-reactive	CAS	Yes	JG - 07/10/28
	Positive	P0203 Expires Dec 17 2008	X2E Expires Nov 30 2008	Reactive	CAS	Yes	

Incident Log

(tracking results that require action)

Location: Hassle Free Clinic Site #: XXXX Month: September Year: 2008

Date	Type of Incident (QC failure, device failure, EQA discrepancy, parallel testing discrepancy)	Description	Action Taken	Date Resolved
Sep 5/07	Invalid result	No control dot, maybe not enough blood collected	Repeated test and worked ok	Sep 5/07 CAS

Environmental Monitoring Log

Location: Site #: Year: 2008

Jan	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Review
Current Temp																																
Min Temp																																
Max Temp																																
Feb	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29			
Current Temp																																
Min Temp																																
Max Temp																																
March	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Current Temp																																
Min Temp																																
Max Temp																																
April	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30		
Current Temp																																
Min Temp																																
Max Temp																																

May	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Review
Current Temp																																
Min Temp																																
Max Temp																																
June	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30		
Current Temp																																
Min Temp																																
Max Temp																																
July	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Current Temp																																
Min Temp																																
Max Temp																																
Aug	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Current Temp																																
Min Temp																																
Max Temp																																

Sept	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30		Review
Current Temp																																
Min Temp																																
Max Temp																																
Oct	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Current Temp																																
Min Temp																																
Max Temp																																
Nov	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30		
Current Temp																																
Min Temp																																
Max Temp																																
Dec	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Current Temp																																
Min Temp																																
Max Temp																																

AIDS Hotline
416-392-2437 or 1-800-668-2437
French: 1-800-267-7432

http://www.health.gov.on.ca/hiv/providers

Catalogue No. CIB-2252849
ISBN 978-1-4249-5770-5

200 September/08